[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 17-10736

D.C. Docket No. 0:16-cv-60471-DPG

DENNIS GODELIA,
individually and as personal representative of the Estate of Debra Godelia,
S.Y.,
surviving minor child of Debra Godelia,

Plaintiffs - Appellants,

versus

John Doe 1, et al.,

Defendants,

ZOLL SERVICES, LLC,
as successor in interest to ZOLL Lifecor Corporation,
SAMANTHA ORSINI,
ANA CECELIA-MASTERS,

Defendants - Appellees.

Appeal from the United States District Court
for the Southern District of Florida

(February 8, 2018)

Before MARTIN, JORDAN, and GINSBURG,* Circuit Judges.

MARTIN, Circuit Judge:

Dennis Godelia and Sterling Youmas appeal the District Court's dismissal of their case against ZOLL Services, LLC ("ZOLL"), which brought seven claims under Florida law. Mr. Godelia is suing individually and as the personal representative of the estate of Debra Godelia, who was his wife. Mr. Youmas was Ms. Godelia's son. Ms. Godelia went into cardiac arrest while wearing an external defibrillator device manufactured by ZOLL, and known as the LifeVest. Ms. Godelia died as a result of this heart attack. The claims against ZOLL for strict products liability, negligence, fraudulent misrepresentation, fraudulent marketing and promotion, breach of express warranty, negligent misrepresentation, and negligent infliction of emotional distress all relate to the operation (or failure to operate) of Ms. Godelia's LifeVest. After careful consideration, and with the benefit of oral argument, we affirm the District Court's dismissal of the plaintiffs' negligent infliction of emotional distress claim. However, in light of developing and binding precedent in our circuit, we reverse the District Court's dismissal of the remaining claims.

* Honorable Douglas H. Ginsburg, United States Circuit Judge for the District of Columbia Circuit, sitting by designation.

I. BACKGROUND

A. THE FACTS

Because we are reviewing the District Court's ruling based on the pleadings, we accept the factual allegations in the complaint as true, and indeed we construe them in the light most favorable to the plaintiffs. Hill v. White, 321 F.3d 1334, 1335 (11th Cir. 2003) (per curiam). Our account of the facts therefore comes from the plaintiffs' complaint.

ZOLL designs, manufactures, and markets the LifeVest, which is a wearable, external defibrillator designed for patients at risk of sudden cardiac arrest. The LifeVest is designed to detect a threatening heartbeat pattern, then administer a treatment shock, for the purpose of restoring the normal heart rhythm. The Food and Drug Administration ("FDA") originally approved the LifeVest for sale in 2001 and classified it as a Class III medical device, which is the highest risk category. A LifeVest must be prescribed by a doctor. But once the LifeVest has been prescribed, ZOLL enters into a contract directly with the patient and the patient's insurance provider.

ZOLL advertised the LifeVest as providing "constant monitoring, immediate protection, and [] peace of mind for patients" and family members. According to ZOLL, "if [a] patient experiences a life-threatening heart rhythm, the LifeVest will detect the rhythm and will deliver a treatment shock to restore the normal heart

rhythm." ZOLL also advertised the LifeVest as having "a 98 percent first treatment shock success rate for resuscitating patients."

On November 1, 2013, Ms. Godelia went to the hospital complaining of abdominal and back pain. When medical staff recognized she was having a heart problem, she was admitted for urgent cardiac catheterization. Before she was discharged, a ZOLL employee, Samantha Orsini, spoke with Ms. Godelia about using a LifeVest. According to the complaint, Ms. Godelia "had significant reservations about and was reluctant to use the LifeVest." Among other things, she was concerned "that the LifeVest would administer a shock when one was not needed and that it would detect a treatable heart event, but fail to administer the shock." In response to Ms. Godelia's concerns, Ms. Orsini told her: (1) the LifeVest would never administer a shock when one wasn't needed; (2) it would administer a shock if a heart event was detected; (3) the success rate for detecting and administering a shock was higher than 98%; and (4) that LifeVest had a 98% first treatment shock success rate for resuscitating patients. Relying on these representations, Ms. Godelia agreed to use the LifeVest and did not ask about alternative treatment options. But because she still had concerns about the product, Ms. Godelia asked for another ZOLL representative to visit her at her home. Ana Cecilia Masters, another ZOLL employee, met with Ms. Godelia and made substantially similar representations. Ms. Godelia continued wearing a LifeVest.

On November 18, 2013, Ms. Godelia went to the doctor, who confirmed that she was using the LifeVest as ZOLL had instructed. Later that same day, Ms. Godelia experienced a "Defibrillation Event" and lost consciousness. The LifeVest detected a problem with Ms. Godelia's heart, making an audible alarm. However, the LifeVest did not shock Ms. Godelia as it was supposed to. Mr. Godelia saw this happen but, following the instructions of ZOLL, he did not touch his wife. Ms. Godelia's son, Mr. Youmas, called 911. When Mr. Youmas realized the shock wasn't being administered, he began performing CPR on his mother. Ms. Godelia remained unconscious and died two days later, on November 20, 2013.

Then came September 23, 2014, when the FDA sent ZOLL a Warning Letter. The letter said the FDA had conducted an inspection of ZOLL's facilities between May 22 and June 20, 2014, and as a result of that inspection, determined that the medical devices ZOLL produced were "adulterated within the meaning of Section 501(h) of the [Federal Food, Drug, and Cosmetic] Act." The letter listed a number of regulatory violations identified by FDA inspectors relating to quality control procedures at the ZOLL manufacturing facility.[1] But the letter was also

[1] Specifically, the Warning Letter identified the following violations: (1) "Failure to document results for corrective and preventive actions, as required by 21 CFR 820.100(b)"; (2) "Failure to review, evaluate, and investigate complaints by a designated unit, as required by 21 CFR 820.198(a)"; (3) "Failure to adequately establish procedures for design validation, as required by 21 CFR 820.30(g)"; (4) "Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals, and with

clear that the list of regulatory violations was not all-inclusive. The letter also referenced problems with LifeVests administering "inappropriate shocks," some of which were caused by noise or vibration, and difficulties in using the device by patients with cognitive or physical limitations.

B. PROCEDURAL HISTORY

On November 17, 2015, Mr. Godelia[2] filed a complaint in Florida state court relating to the malfunction of Ms. Godelia's LifeVest. The suit was brought against ZOLL and two unknown ZOLL representatives, later identified as Ms. Orsini and Ms. Masters.[3] On March 9, 2016, ZOLL removed the case to federal court.

---

sufficient frequency, according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c)"; (5) "Failure to report to us no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that your firm markets may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1)"; (6) "Failure to report to us no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2)"; (7) "Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17."

[2] As noted above, the complaint was filed by Mr. Godelia, individually and as personal representative of the estate of Ms. Godelia, together with Mr. Youmas. Although the case caption refers to S.Y. as a minor, he has now reached majority, so we use his name. For simplicity, we will refer to the claims as brought by Mr. Godelia.

[3] The parties have since asked this Court to dismiss Ms. Orsini and Ms. Masters, which we have done in a separate order.

Mr. Godelia then amended his complaint, raising eight claims for relief: (1) strict products liability based on a manufacturing defect; (2) negligence based on a manufacturing defect; (3) fraudulent misrepresentation; (4) fraudulent omission and concealment; (5) fraudulent marketing and promotion; (6) breach of express warranty; (7) negligent misrepresentation; and (8) negligent infliction of emotional distress. Mr. Godelia said the LifeVest had a manufacturing defect that caused it to fail, and that the defect "was the direct result of ZOLL's failure to comply with relevant federal regulations in the manufacturing of the LifeVest." Mr. Godelia based these claims on violations of regulations implementing the Medical Device Amendments ("MDA") that were identified in the FDA Warning Letter, although he noted that the Warning Letter itself said its list of violations was not all-inclusive. Mr. Godelia said the violations described in the Warning Letter "also existed at the time the subject LifeVest was manufactured in May 2013." Mr. Godelia also based a number of his claims on statements made by ZOLL and its employees, which he said overstated the effectiveness of the LifeVest.

Ten days after Mr. Godelia filed the amended complaint, ZOLL moved to dismiss it. ZOLL argued that the MDA preempted all of Mr. Godelia's claims. In response, Mr. Godelia acknowledged that the District Court would be justified in dismissing his fraudulent omission and concealment claim on preemption grounds,

and he dropped that claim. But he stood by the remaining claims, saying they should survive under both Florida and federal law.

The District Court then granted ZOLL's motion to dismiss in full. Indeed, the District Court determined that all of Mr. Godelia's claims were expressly preempted by the MDA because they were premised on the LifeVest being defective. The District Court reasoned that claims of defects in the LifeVest would be at odds with the FDA's determination that LifeVests were safe. The District Court also found that Mr. Godelia failed to allege a parallel claim, as is required in order to avoid preemption, because "there is no nexus between the warning letter, Ms. Godelia's LifeVest, and her injuries." In addition, the District Court held that the breach of express warranty claim failed under Florida law because there was no privity between Ms. Godelia and ZOLL, and that the negligent infliction of emotional distress claim failed under Florida law because Mr. Godelia and Mr. Youmas did not "allege a discernible physical injury." Finally, the court said that even if some of the plaintiffs' claims were not expressly preempted, they were likely impliedly preempted.

This appeal followed. After Mr. Godelia filed his brief on appeal, but before ZOLL filed its answer brief, this Court issued its decision in Mink v. Smith & Nephew, Inc., 860 F.3d 1319 (11th Cir. 2017). Mink addressed preemption

questions very much like those raised here, and brought under similar circumstances.

II. STANDARD OF REVIEW

We review de novo the District Court's dismissal of a complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Hill, 321 F.3d at 1335. In doing so, we accept the plaintiff's allegations in the complaint as true, and we construe them in the light most favorable to the plaintiff. Id. Even so, "only a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950 (2009). We also review de novo the District Court's interpretation of state law. Tampa Bay Water v. HDR Eng'g, Inc., 731 F.3d 1171, 1177 (11th Cir. 2013).

III. FEDERAL PREEMPTION LAW

We begin with a brief overview of the law governing medical devices. The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq., give the FDA regulatory authority over medical devices. Mink, 860 F.3d at 1325. Class III devices like the LifeVest, which are deemed the highest risk, are required to go through an extensive premarket approval process. See Riegel v. Medtronic, Inc., 552 U.S. 312, 317–18, 128 S. Ct. 999, 1003–04 (2008). Once a device has been approved, a manufacturer may not make any change to the device that could affect

its safety or effectiveness unless that change gets additional approval from the FDA. Id. at 319, 128 S. Ct. at 1005.

The MDA provides for two types of preemption of certain state law claims relating to medical devices: express and implied. The express preemption provision bars any claim based on a state law requirement "which is different from, or in addition to, any requirement" under the MDA that "relates to the safety or effectiveness of the device" or any other MDA requirement. 21 U.S.C. § 360k(a). The implied preemption provision of the MDA states that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." Id. § 337(a). The Supreme Court has interpreted this implied preemption provision to bar claims that merely attempt to enforce duties owed to the FDA, so-called "fraud-on-the-FDA claims." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348, 121 S. Ct. 1012, 1017 (2001).

Taken together, these two types of preemption leave a "narrow gap" through which plaintiffs making medical device claims must proceed. See In re Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010). "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." Mink, 860 F.3d at 1327. Put differently, "a plaintiff may proceed on her claim so long as she claims the 'breach of a well-

recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" Id. (quoting Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010)).

IV. MR. GODELIA'S CLAIMS

Mr. Godelia has seven remaining Florida state law claims: (1) strict products liability based on a manufacturing defect; (2) negligence based on a manufacturing defect; (3) fraudulent misrepresentation; (4) fraudulent marketing and promotion; (5) breach of express warranty; (6) negligent misrepresentation; and (7) negligent infliction of emotional distress.

"Because preemption is a principle derived from the Supremacy Clause, U.S. Const. Art. VI, cl. 2, we must first analyze whether each claim can stand under state law, and only then decide the preemption questions where necessary." Id. at 1328. As a result, we will first examine each claim under Florida law and only if it is viable under state law, will we then consider whether it is expressly or impliedly preempted.

A. CLAIMS BASED ON MANUFACTURING DEFECT

Mr. Godelia's complaint raises two claims based on a manufacturing defect: strict products liability and negligence. Mr. Godelia says his wife's LifeVest "was defective and unreasonably dangerous as a result of a manufacturing defect." He also says that the "manufacturing defect was the direct result of ZOLL's failure to

comply with applicable federal regulations noted above for manufacturing LifeVest devices, including the subject LifeVest, and for detecting and fixing manufacturing defects with LifeVest devices before placing them into the stream of commerce."

Mr. Godelia bases his claims on violations of federal law identified in the FDA Warning Letter, "including by way of example, sections 21 CFR 820.100(b), 21 CFR 820.198(a), 21 CFR 820.30(g), 21 CFR 820.20(c)." However, Mr. Godelia stresses the Warning Letter "is not an all-inclusive list of every possible violation of deviation from law and regulation observed during the FDA Inspection." He says ZOLL's "failure to comply with the above regulations resulted in Zoll failing to determine that the subject LifeVest was manufactured and delivered to Debra Godelia with non-conformities."

The District Court found Mr. Godelia's strict products liability and negligence claims based on a manufacturing defect to be expressly preempted by the MDA. The court also found Mr. Godelia had not established a causal connection between the alleged violations and Ms. Godelia's injury. The court then also made the alternative ruling that Mr. Godelia's claims were impliedly preempted because there is no private right of action for a violation of the FDCA. To reach this result, the District Court in Mr. Godelia's case relied on the

preemption analysis from a District Court ruling in Mink, which this Court later reversed on appeal. 860 F.3d at 1330–31.

1. Florida State Law

Florida law recognizes strict liability claims based on a manufacturing defect. See West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976). To make a strict liability claim under Florida law, a plaintiff "must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages." Id.

Florida also recognizes negligence claims in relation to manufacturing defects. See Ford Motor Co. v. Evancho, 327 So. 2d 201, 204 (Fla. 1976) ("[T]he manufacturer must use reasonable care in design and manufacture of its product to eliminate unreasonable risk of foreseeable injury."). In Florida, "a manufacturer's duty to inspect and test . . . . is a subpart of a manufacturer's duty to design a product with reasonable care." Adams v. G.D. Searle & Co., 576 So. 2d 728, 730–31 (Fla. 2d DCA 1991). And in Florida, "the violation of a statute may be utilized as evidence of negligence." Fla. Dep't of Corr. v. Abril, 969 So. 2d 201, 205 (Fla. 2007).

Here, Mr. Godelia says ZOLL manufactured the LifeVest and placed it into commerce, the LifeVest was defective and nonconforming, and that those defects

caused Ms. Godelia's injuries. Mr. Godelia also says the "violation of the federal regulations noted above" caused the defect in Ms. Godelia's LifeVest. On its face, this is sufficient to state a claim under Florida law for strict liability and negligence related to a manufacturing defect. Contrary to ZOLL's argument, Mr. Godelia need not state in his complaint the precise defect that caused Ms. Godelia's LifeVest to malfunction. See Small v. Amgen, Inc., 2 F. Supp. 3d 1292, 1297 (M.D. Fla. 2014).

The District Court's finding that Mr. Godelia did not show an adequate nexus between the regulatory violations and Ms. Godelia's injury—apparently, a determination that Mr. Godelia did not adequately plead causation—is also misplaced. While it may come to pass that Mr. Godelia has a difficult time proving that it was the violations of the MDA regulations that caused a defect in Ms. Godelia's LifeVest, the allegations in his complaint are sufficient to state a claim that is plausible on its face. See Iqbal, 556 U.S. at 678, 129 S. Ct. at 1949. For example, it is plausible that ZOLL's failure to document and respond to complaints about its products in violation of 21 CFR 820.198(a) could have resulted in a defect persisting in LifeVests long after ZOLL should have been aware of it, and that this defect caused Ms. Godelia's death. We decline ZOLL's invitation to apply a heightened pleading standard to allegations of causation in medical device claims. Cf. Leatherman v. Tarrant Cty. Narcotics Intelligence &

Coordination Unit, 507 U.S. 163, 168, 113 S. Ct. 1160, 1163 (1993). Mr. Godelia's claims under Florida law for negligence and strict liability based on a manufacturing defect are sufficiently pled.

2. Express Preemption

ZOLL argues that Mr. Godelia's manufacturing defect claims are all expressly preempted because he "did not allege that the common law claims were based solely on the violation of" the MDA regulations. ZOLL says "[a]s alleged, all of the counts could proceed even if ZOLL had complied with federal law because the complaint allowed liability to be premised on findings that ZOLL had been negligent or had produced an unreasonably dangerous product, apart from any federal regulatory violation."

We conclude to the contrary that Mr. Godelia has sufficiently pled his strict liability and negligence claims so as to avoid express preemption. Mr. Godelia alleged that "[t]he manufacturing defect was the direct result of Zoll's failure to comply with applicable federal regulations noted above." In his Reply Brief (now with the benefit of this Court's decision in Mink), Mr. Godelia reiterates that his claims "are premised only on Zoll's violations of federal regulations, which also caused a violation of Florida's common law duty to use due care in manufacturing the LifeVest." This Court recognized in Mink that both Florida negligence and strict liability claims based on manufacturing defects can survive express

preemption. 860 F.3d at 1330–31. We see no basis for distinguishing Mr. Godelia's and Mr. Mink's claims in this regard.

ZOLL would have us dismiss Mr. Godelia's claims because his complaint didn't expressly limit them to violations of federal regulations. But that would verge on requiring plaintiffs to invoke magic words in their complaints. Cf. Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1054 (11th Cir. 2015) (holding that plaintiff's "failure to include the adverb solely—a word with no talismanic power—is not enough to preclude the inference that he pleaded a plausible violation of the False Claims Act"). Here at the pleadings stage, Mr. Godelia has satisfactorily limited his claims to violations of federal regulations. If they should later be shown to extend beyond the purview of the applicable federal regulations, his claims may be defeated at that point.

Mr. Godelia has also met his burden to plead specific violations of federal regulations. In Wolicki-Gables v. Arrow International, Inc., 634 F.3d 1296 (11th Cir. 2011), this Court held that a plaintiff's Florida manufacturing defect claims were expressly preempted in part because the plaintiffs did "not set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." Id. at 1301–02 (quotation omitted). This case is different. Mr. Godelia alleged the violation of the specific federal regulations identified in the FDA Warning Letter. The fact that the regulations identified are not device-

specific is of no moment. See Mink, 860 F.3d at 1331 n.3 ("To the extent [the defendant] argues that some of the federal regulations cited by [the plaintiff] are not sufficiently device-specific, we reject its argument. We agree with our sister circuits that there is no sound legal basis to distinguish these federal requirements because the plain text of 360k refers to 'any requirement.'" (quotation omitted)).

We are mindful that Mr. Godelia would not likely have an opportunity to access documents describing all of the LifeVest-specific regulatory requirements without discovery. As the Seventh Circuit recognized, "[t]he specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery." Bausch, 630 F.3d at 560. In any event, Mr. Godelia has alleged a violation of federal regulations sufficient to avoid express preemption under the MDA.

3. Implied Preemption

ZOLL also argues that Mr. Godelia's claims are impliedly preempted because the specific federal regulations Mr. Godelia alleges were violated sound more like "fraud-on-the-FDA" claims than traditional state law tort claims. This argument misses the mark. While Mr. Godelia's claims would have been impliedly preempted if he were asking the court to find ZOLL liable based solely on a failure to report to the FDA, Mr. Godelia is not pursuing this type of claim.

Instead, Mr. Godelia is claiming negligence and strict liability based on a manufacturing defect, and in order to succeed, he will have to prove all the elements of those claims under Florida law. Again, we find Mink controlling on this point. There, we concluded that Mr. Mink's strict liability and negligence claims based on a manufacturing defect were not impliedly preempted because "the duty enforced here is the traditional state tort duty of a manufacturer to use due care in manufacturing." Mink, 860 F.3d at 1331. And as already noted, in Florida, a manufacturer's duty includes the duty to inspect and test. See Adams, 576 So. 2d at 730–31. Mr. Godelia's strict liability and negligence claims are sufficient on the pleadings to avoid implied preemption. Because these claims are sufficient under state law, and are not expressly or impliedly preempted, we reverse the District Court's dismissal.

B. CLAIMS BASED ON REPRESENTATIONS

Mr. Godelia also makes a number of claims based on representations made by ZOLL about the efficacy of the LifeVest. His claims include fraudulent misrepresentation, negligent misrepresentation, fraudulent marketing and promotion, and breach of express warranty.

Mr. Godelia says ZOLL and its employees made affirmative misrepresentations to the Godelias that contained material facts they knew or should have known were false. Specifically, he says ZOLL advertised that the

LifeVest would provide "constant monitoring, immediate protection, and [] peace of mind for patients," and that the LifeVest had a "98 percent first treatment shock success rate for resuscitating patients." Mr. Godelia also says Ms. Orsini and Ms. Masters told Ms. Godelia that the LifeVest would never administer a shock when one wasn't needed, and that it would administer a shock whenever one was needed. Because ZOLL did not have procedures to evaluate how effective LifeVests actually were, Mr. Godelia says "Zoll could not know and did not know the success rate of the LifeVest." Mr. Godelia says that these misrepresentations induced his wife to wear a LifeVest.

1. Florida State Law

To make a claim for fraudulent misrepresentation under Florida law, a plaintiff must allege: "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation." Butler v. Yusem, 44 So. 3d 102, 105 (Fla. 2010) (emphasis removed). A party alleging negligent misrepresentation makes a valid claim "only if the recipient of the information justifiably relied on the erroneous information." Gilchrist Timber Co. v. ITT Rayonier, Inc., 696 So. 2d 334, 337 (Fla. 1997).

The District Court treated Mr. Godelia's fraudulent and negligent misrepresentation claims identically, and neither party has given us reason to distinguish them now. Mr. Godelia said ZOLL and its employees made the false statements described in the complaint to Ms. Godelia with the intent to sell their product, that ZOLL and its employees knew or should have known that those statements were false, and that Ms. Godelia reasonably relied on those statements when she purchased the LifeVest that caused her injury. This is sufficient to state a claim under Florida law for both fraudulent misrepresentation and negligent misrepresentation.

Next, Mr. Godelia's fraudulent marketing and promotion claim is based on Florida Statutes Sections 817.40(5) and 817.41(1). Among other things, these laws make it "unlawful for any person to make or disseminate or cause to be made or disseminated . . . any misleading advertisement." Fla. Stat. § 817.41(1). A "misleading advertisement" is defined as statements made with the purpose of selling property or services "which are known, or through the exercise of reasonable care or investigation could or might have been ascertained, to be untrue or misleading." Fla. Stat. § 817.40(5). Mr. Godelia points to specific marketing statements he says were false and misleading, noting that ZOLL could not and did not have a factual basis for making those statements. This is sufficient to state a claim under Florida law for fraudulent marketing and promotion.

Finally, Mr. Godelia brings a claim for breach of express warranty. The District Court stated that under Florida law, a breach of express warranty claim requires privity of contract between the parties. The court found no privity of contract here, stating: "Plaintiffs allege that Mrs. Godelia required a prescription to obtain the LifeVest. As such, Mrs. Godelia could not purchase the device directly from Defendants." Our review of Florida law reveals no clear rule about whether privity is required in every Florida express warranty claim. Compare T.W.M. v. Am. Med. Sys., 886 F. Supp. 842, 844 (N.D. Fla. 1995) (stating that privity is required for all express warranty claims), with Smith v. Wm. Wrigley Jr. Co., 663 F. Supp. 2d 1336, 1342–43 (S.D. Fla. 2009) (recognizing that privity may not be required for all express warranty claims). But even if we assume privity is required, Mr. Godelia has sufficiently alleged it. We see no basis for the broad rule articulated by the District Court that there can be no privity when a prescription is required for purchase. Here, Mr. Godelia alleged that his wife contracted directly with ZOLL to purchase her LifeVest, and ZOLL has made no showing to the contrary. At this stage in the proceedings, and accepting Mr. Godelia's allegations as true, he has sufficiently stated a claim for breach of express warranty under Florida law.

2. Express and Implied Preemption

In Mink, this Court concluded that the plaintiff's fraudulent misrepresentation claim was not expressly or impliedly preempted. 860 F.3d at 1333. In so holding, we said that if any representations by the manufacturer imposed new requirements on its products, those requirements "were undertaken by [the manufacturer], not imposed by the state of Florida." Id. And because the MDA only preempted regulations imposed by the state, there was no preemption problem for claims arising from the statements manufacturers make about their products. Id. The Mink opinion found support for this proposition in a Supreme Court ruling that determined breach of express warranty claims were not preempted by another federal statute. See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525, 112 S. Ct. 2608, 2622 (1992) ("A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the requirements imposed by an express warranty claim are not imposed under State law, but rather imposed by the warrantor." (quotations omitted and alteration adopted)).

The same reasoning controls here. If ZOLL's various statements held its product out as meeting a higher standard than that required by the FDA, this was ZOLL's independent undertaking. ZOLL could have chosen to promise its patients less, but that may have resulted in patients not choosing to use a LifeVest.

Because Mr. Godelia's claims for fraudulent misrepresentation, negligent misrepresentation, fraudulent marketing and promotion, and breach of express warranty are traditional state-law claims and address promises made by ZOLL rather than imposed by the state, we conclude that these claims are not impliedly or expressly preempted. Because these claims are also sufficient under state law, we reverse the District Court's ruling that dismissed them.

C. NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

The plaintiffs' last claim is for negligent infliction of emotional distress. Mr. Godelia and Mr. Youmas say that "[a]s a result of witnessing the sad and devastating death of Debra Godelia, [they] suffered and continue to suffer emotional distress and damages, which . . . have manifested into physical symptoms." Specifically, Mr. Godelia says he has experienced "insomnia, depression, short-term memory loss, inability to stop reliving [] Debra Godelia's death, muscle and stomach pain." Mr. Youmas says he suffers from an "inability to stop reliving the event, depression, short-term memory loss, muscle and other pain."

1. Florida State Law

In Florida, "persons who suffer a physical injury as a result of emotional distress arising from their witnessing the death or injury of a loved one may maintain a cause of action for negligent infliction of emotional distress." Zell v.

Meek, 665 So. 2d 1048, 1050 (Fla. 1995). In Zell, the Florida Supreme Court concluded that the plaintiff had shown a physical injury sufficient to make a claim for negligent infliction of emotional distress. Id. at 1054. The plaintiff in Zell saw a physician for treatment of severe pain below her rib cage and in her chest, a blockage in her esophagus, irritable bowel symptoms, and joint pain, all of which resulted from her proximity to a bomb that exploded at the door of her parents' apartment. Id. at 1049–50. The physician said that the psychological trauma the plaintiff suffered contributed to her physical symptoms and increased her need for medical care. Id. at 1050. In contrast, in R.J. v. Humana of Fla., Inc., 652 So. 2d 360 (Fla. 1995), the Florida Supreme Court held that general allegations of "bodily injury including hypertension, pain and suffering" resulting from a wrong report about the result of a blood test were not sufficient to state a claim for negligent infliction of emotional distress. Id. at 364.

Our review of Florida law leads us to conclude that Mr. Godelia and Mr. Youmas have failed to allege a physical injury sufficient to state a claim for negligent infliction of emotional distress. Their generalized allegations of muscle and stomach pain appear closer to the symptoms deemed insufficient in R.J. than those found sufficient in Zell. Because the plaintiffs' negligent infliction of emotional distress claim is not sufficient under Florida law, we affirm the District Court's dismissal of this claim. If the plaintiffs' symptoms have manifested into

more concrete physical injuries, those facts would properly be the subject of an amendment to the complaint.

V. CONCLUSION

We affirm the District Court's dismissal of Mr. Godelia's negligent infliction of emotional distress claim. We reverse the District Court's dismissal of Mr. Godelia's remaining claims, which we conclude are cognizable Florida common law causes of action and are not preempted by federal law.

AFFIRMED IN PART, REVERSED AND REMANDED IN PART